NOTE: All systems and products should be considered as investigational-use only in the context of the NIH BRAIN Initiative.

VERCISE™ DEEP BRAIN STIMULATION SYSTEM

Description: 16-channel rechargeable implantable pulse generator. Each of the 16 current controlled electrode contacts of the pulse generator can be programmed independently as an anode or a cathode and assigned -100% to +100% (1% step size) of the total current. This unique feature is designed to allow for precise control of the stimulation field and provide stability of the field over time. The size is 22 cc including the header.

Specifications:

Parameter	Range
Amplitude[a]	0.1 – 20 mA
Rate[b]	2-255 Hz
Pulse Width	10-450 µs
Cycle (On/Off)	1s – 90 min
Stim Ramp ON	1 – 10 s
Independent Areas of Stim (4 Programs with 4 Areas per Program)	16

a) The programmable coverage for each individual contact is limited to 12.7mA. A programming interlock is enforced to limit the total output current to 0mA or less per coverage area. For example, a maximum current output of 12.7mA on one contact would limit the total summed current output on the remaining contacts to 7.3mA within one coverage area.

b) The rate is limited to 255Hz for a given area.

VERCISE™ PC DEEP BRAIN STIMULATION SYSTEM

Description: Similar to Vercise DBS rechargeable system in terms of capabilities but uses a primary cell battery and has a different form factor (33cc including the header).

GUIDE™ DBS SOFTWARE

Description: GUIDE™ DBS Software (GUIDE DBS) is a simulation system that allows the clinician to plan the programming of a patient with a Boston Scientific Deep Brain Stimulation (DBS) System. GUIDE DBS provides:

- A view of the Lead(s) relative to the deep brain structures associated with treatment
- The tools for simulating neuron response to stimulation
- A visual model of the stimulation field in the context of an anatomical atlas.

Using GUIDE DBS, one can determine a starting point for the monopolar review that may reduce programming time.

8-CONTACT DEEP BRAIN STIMULATION LEAD

Description: The DBS Lead consists of 8 cylindrical contacts. The outer diameter of the DBS Lead
and contacts is 1.3 mm and is compatible with existing commercially available DBS implantation tools.
The DBS Lead can be implanted and attached to the stimulator for both unilateral stimulation (on either
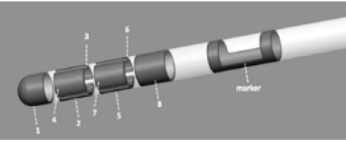the left or right side) and bilateral stimulation.

Specifications:

Feature	Description
Number of contacts	8
Contact Length	1.5mm
Contact spacing (center to center)	2.0mm
Contact span	15.5mm
Distal contact to tip	<1.3mm
Diameter	1.3mm
Overall Length	30cm, 45cm
Outer Jacket tubing (insulation)	Polyurethane
Contact Material	Platinum/Iridium
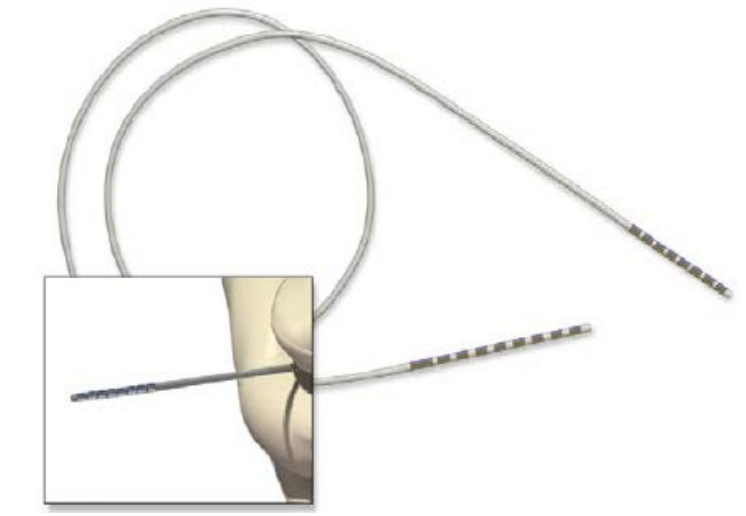
DIRECTIONAL 8 CONTACT SEGMENTED DEEP BRAIN STIMULATION LEAD

Description: Eight-contact segmented lead with current steering.

Feature	Specification
Tip Length	1.5 mm
Contact Length	1.5 mm
Contact Spacing (axial)	0.5 mm
Lead Diameter	1.3 mm
Overall Length	30 cm or 45 cm
Outer Tubing Material	Polyurethane
Contact Material	Platinum/Iridium
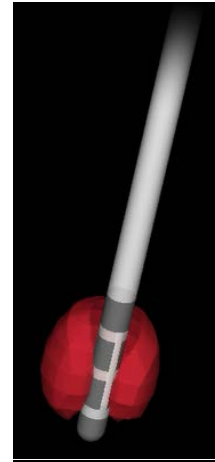
PRECISION SPECTRA™ SPINAL CORD STIMULATOR SYSTEM

Description: 32-channel rechargeable implantable pulse generator. Each of the 32 current-controlled electrode contacts of the pulse generator can be programmed independently as an anode or a cathode and assigned -100% to +100% (1% step size) of the total current. This unique feature is designed to allow for precise control of the stimulation field and provide stability of the field over time. The size is 21.2 cc including the header.

Specifications:

Parameter	Range
Areas	4
Amplitude	0-25.5mA
Rate	2-1200pps[a]
Pulse Width	20-1000µs[b]
Cycle	1s-90min, OFF
Ramp ON	1-10s
Contacts	1-32, case: +100% to -100%, OFF

a) Only one Area is available if the rate is >130pps
b) Amplitude x Width ≤12.7uC for all leads other than the 4x8 Surgical lead; Amplitude X Width<9.1uC for the 4x8 Surgical Lead

PRECISION™ SPINAL CORD STIMULATOR SYSTEM

Description: Similar to Precision Spectra but with 16 channels of multiple independent current control instead of 32. Size is the same as Spectra.

Specifications:

Parameter	Range
Areas	4
Amplitude	0-20mA[a]
Rate	2-1200pps[b]
Pulse Width	0-1000µs
Cycle	0s-90min, OFF
Ramp ON	1-10s
Contacts	1-16: +100% to -100%, OFF

a) The Precision system includes programmable coverage areas with each individual electrode contact limited to 12.7mA. A programming interlock is enforced to limit the coverage area output current to 20mA or less. For example, a maximum current output of 12.7mA on a first electrode will limit the total summed current output on remaining electrodes to 7.3mA within one coverage area.

b) Only one Area is available if the rate is 130pps.

PRECISION NOVI™ SPINAL CORD STIMULATOR SYSTEM

Description: Similar to Precision with 16 channels of multiple independent current control but utilizing a primary cell battery and a different form factor (33cc including the header).

Specifications: Refer to Precision Spectra summary above.

PRECISION MULTIWAVE™ SPINAL CORD STIMULATOR SYSTEM

Description: Similar to Precision with 16 channels of multiple independent current control but capable of stimulation frequencies up to 10kHz.

Specifications:

For frequencies 1200Hz or lower

Parameter	Range
Areas	4
Amplitude	0-20 mA[a] (0.1mA step size)
Rate	2-1200 pps[b]
Pulse Width	0-1000 µs (10us step size)
Cycle	0s-90 min, OFF
Ramp ON	1-10s
Contacts	1-16: +100% to -100%, OFF

a) The Precision system includes programmable coverage areas with each individual electrode contact limited to 12.7mA. A programming interlock is enforced to limit the coverage area output current to 20mA or less. For example, a maximum current output of 12.7mA on a first electrode will limit the total summed current output on remaining electrodes to 7.3mA within one coverage area.
b) Only one Area is available if the rate is 130pps.

For frequencies greater than 1200Hz

Parameter	Range
Areas	1
Amplitude	0-9 mA
Rate	2-10 kHz
Pulse Width	20-240 µs[a]
Cycle	3-90 min, OFF
Ramp ON	1-3s
Contacts	1-16: +100% to -100%, OFF[b]

a) In increments of 10usec, range of available pulse width will depend on the programmed frequency rate.
b) Maximum of 1 anode and 1 cathode are programmable.

PERCUTANEOUS SPINAL CORD STIMULATOR LEADS

Description: Various 1x8 contact electrode leads with 3 different electrode spacing configuration and 1x16 electrode contacts percutaneous linear lead configuration.

Additional information can be found at: http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/91078744-01RevA_Percutaneous_Leads_DFU_en-US_S.pdf

SURGICAL PADDLE SPINAL CORD STIMULATOR LEADS

Description: 4x8 and 2x8 surgical paddle lead configurations are available.

Additional information can be found at: http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/91078747-01RevA_Surgical_Leads_DFU_en-US_S.pdf
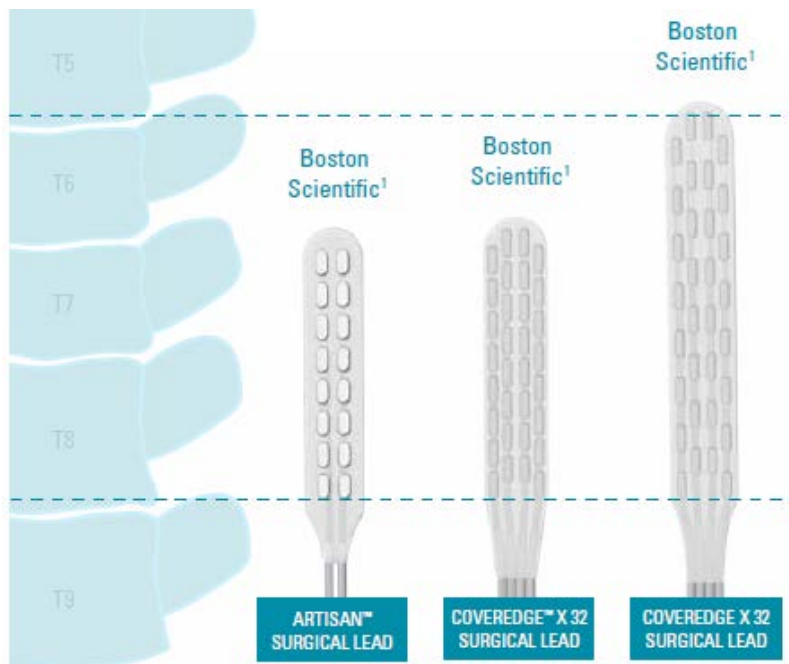
Accessories such as connectors and adapters for connection to other manufacturers' leads:

M8 Connector: allows connection to selected Medtronic leads to a Boston Scientific pulse generator

http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90893429-09RevA_Precision_M8_Adapter_DFU_en-US_S.pdf

S8 Connector: allows connection to selected St Jude leads to a Boston Scientific pulse generator

http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90893896-01_RevB_Precision_S8_Adapter_DFU_en-US_S.pdf

OMG connector: allows connection to selected Medtronic and St Jude leads to a Boston Scientific external trial stimulator during a trial evaluation period

http://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/90870349-01_RevA_Precision_Spectra_OMG_US_S.pdf

Additional information for Spinal Cord Stimulator products can be found at:
http://www.bostonscientific.com/manuals/manuals/landing-page/US-english.html

If a partnership requires Boston Scientific support, the following services may be made available:

- Lead prototyping.
- Firmware modifications to the Implantable pulse generators (IPG).
- Software modifications to the computer programmers (CP).
- Use of advance computational models and predictive algorithms for parameters and programming guidance for spinal cord stimulation and deep brain stimulation.